510(k) Number K052371

MAY - 4 2006

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

510(k) Summary Statement for MED-OP Aesthetic Technologies, Ltd.
Depilite EL-8b Series DERMO FLASH™ Systems

Regulatory Authority:

Safe Medical Devices Act of 1990, Title 21 C.F.R. Section 807.92

Submitter's Name:

Hair International Systems USA, Inc.
11526 Sorrento Valley Road, Suite 1B
San Diego, California 92121
Tel: (858) 755-5758
Fax: (858) 755-5574

Contact Person:

Amnon Zakay, President and CEO

Name of Devices:

Depilite EL-8b Series DERMO FLASH™ Systems
(and Delivery Accessories):

- DERMO FLASH™ Model A
- DERMO FLASH™ Model SX-513 A
- DERMO FLASH™ Model SX-513 C
- DERMO FLASH™ Model C

Common Names:

Dermatology Flash Lamp Systems

K052371

510(K) PREMARKET NOTIFICATION
Depilite EL-8b Series DERMO FLASH™ Systems
MED-OP Aesthetic Technologies, Ltd.
March 20, 2006

Classification:

Laser surgical instrument for use in general and plastic surgery and in dermatology. Title 21 C.F.R. Section 878.4810

Medical Specialty - General & Plastic Surgery

Device Class II – Special Controls

Product Code – GEX

Panel - 79

Equivalent Devices:

Light-Emitting Source: Flash Lamp Intense Pulsed Light (IPL) Technology:

- Clareon™ Pulsed Light System
  Solarus™ Pulsed Light System
  Novalis Medical, LLC
  K043319, Dec. 17, 2004

- ProLite / Plasmalite MPX Pulsed Light System
  Medical Bio Care Nordic AB
  K023081, Dec. 16, 2002

- Flash 1
  emed, Inc.
  K022583, Oct. 31, 2002

- EpiLight®
  PhotoDerm® HR
  ESC Medical Systems, Ltd.
  K991935, January 27, 2000

K05 2371

510(K) PREMARKET NOTIFICATION
Depilite EL-8b Series DERMO FLASH™ Systems
MED-OP Aesthetic Technologies, Ltd.
March 20, 2006

Description of the DERMO FLASH™ Series Devices:

The Depilite EL-8b Series DERMO FLASH™ devices are microprocessor-controlled nonablative light-based medical devices which use pulsed xenon lamps to deliver a selectable range of polychromatic light outside the range of harmful ultraviolet wavelengths leaving only the visual and infrared light to be presented for photo thermolysis epilation and skin treatments. Pre-set and manual delivery parameters – such as the appropriate wavelength, energy, pulse rate and exposure time – and other system features are modulated from the display and control panel on the main unit. The corresponding fluence is delivered through an air-cooled double lamp hand piece without making contact with the treated area (Non Contact Pulsed Light or NCPL™). The complete system consists of the Depilite EL-8b DERMO FLASH™ machine, a photothermolysis handle with treatment head, keys for main switch, a foot switch, electric power cable, protective goggles, and instruction manual.

The Depilite EL-8b Series DERMO FLASH™ devices are in compliance with mandatory special controls as required by 21 C.F.R. Part 1040 – Performance Standards for Light-Emitting Products.

Indications for Use:

The Depilite EL-8b Series DERMO FLASH™ Systems are microprocessor-controlled nonablative light-based medical devices designed for permanent hair reduction, and the treatment of vascular and benign pigmented lesions and inflammatory acne, on skin types I-IV.

Substantial Equivalency:

The differences in specifications of the Depilite EL-8b Series DERMO FLASH™ devices and the predicate device(s) do not result in different performances or raise new questions of safety or efficacy.

Conclusion:

The Depilite EL-8b Series DERMO FLASH™ Systems are substantially equivalent to other legally-marketed flash light-based medical devices in U.S. commercial distribution for the same dermatological applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2006

Hair International Systems USA, Inc.
c/o Horton, Whiteley & Cooper
Mr. Craig A. Mitchell
4590 Macarther Boulevard – Suite 500
15770 Laguna Canyon Road
Newport Beach, California 92692

Re: K052371
Trade/Device Name: Depilite EL-8B Series DERMO FLASH™ System
DERMO FLASH™ Model A
DERMO FLASH™ Model SX-513 A
DERMO FLASH™ Model SX-513 C
DERMO FLASH™ Model C
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: April 21, 2006
Received: April 25, 2006

Dear Mr. Mitchell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): 510(k) Number K052371

Device Name: Depilite EL-8b Series DERMO FLASH™ Systems

Indications For Use: The Depilite EL-8b DERMO FLASH™ Model A system is a microprocessor-controlled nonablative xenon flash lamp-based medical device designed for permanent hair reduction.

The Depilite EL-8b DERMO FLASH™ Model SX-513a system is a microprocessor-controlled nonablative xenon flash lamp-based medical device designed for permanent hair reduction.

The Depilite EL-8b DERMO FLASH™ Model SX-513c system is a microprocessor-controlled nonablative xenon flash lamp-based medical device designed for permanent hair reduction, and treatment of vascular and benign pigmented lesions and inflammatory acne.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices



510(k) Number K052371

# Indications for Use

510(k) Number (if known): 510(k) Number K052371

Device Name: Depilite EL-8b DERMO FLASH™ Systems

Indications For Use: The Depilite EL-8b DERMO FLASH™ Model C system is a microprocessor-controlled dual nonablative xenon flash lamp-based medical device designed for permanent hair reduction, and treatment of vascular and benign pigmented lesions and inflammatory acne.